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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,879	03/30/2001	Jerry L. Kermicle	WIS4987P0081US	6744

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EXAMINER

FOX, DAVID T

ART UNIT PAPER NUMBER

1638

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/821,879	Applicant(s) KERMICLE ET AL.	
	Examiner David T. Fox	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004 and 15 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5,9-17,21-35,39-50,59-68 and 73-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,9-17,21-35,39-50,59-68 and 73-80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 March 2004 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 48 is objected to under 37 CFR 1.121(c) as being of improper amended format. It appears that claim 48 was amended to replace "39" in line 3 with ---47---. However, correct amendment format dictates the recitation of the originally claimed subject matter with a strikethrough, and underlining of the newly added subject matter. In the interest of compact prosecution, claim 48 is hereby examined. Such treatment does not relieve Applicant of the responsibility of submitting a properly amended claim 48 in response to this Office action.

Applicant's amendments of 15 March 2004 have addressed the errors set forth on page 2 of the last Office action.

Newly submitted claims 73 and 78 are objected to for containing errors. The claims indicate that molecular markers "umc1117" and "bnlg" are found in Figure 1. However, it is Figure 3B that presents markers umc1117, bnlg490 and bnlg1937, wherein umc1117 and bnlg490 are closely linked to the tcb locus, while bnlg1937 is far from the tcb locus. It appears that Applicant intended to recite the umc1117 and

bnlg490 markers from Figure 3B in these claims (see, e.g., page 15 of the response of 15 March 2004, first full paragraph, which also refers to page 18 of the specification, lines 18-19). Claims 73 and 78 should be so corrected.

Claims 1-5, 9-17, 21-35, 39-50, 67-68, 73-77 and 80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-2, 9, 15, 27, 39, 46-47, 49, 73, 76 and dependents recite a "*Tcb* gene cluster". Applicant has not pointed out any basis for this term in the specification, and there appears to be none. Accordingly, the claims are drawn to NEW MATTER.

Claims 9-17, 21-26, 39-50 and 59-68 remain, and new claims 73-80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on page 2 of the last Office action for claims 9-17, 21-26, 39-50 and 59-68.

Applicant's arguments filed 15 March 2004 have been fully considered but they are not persuasive. Applicant urges that the instant specification provides the location of the *Tcb* gene cluster and the *Tcb* locus therein, as well as the approximate location of

the modifier gene, and the molecular markers useful to identify these loci. Applicant urges that the Examiner has not provided sufficient evidence to demonstrate that the skilled artisan would not have recognized Applicant to have been in possession of the claimed invention.

The Examiner maintains that the location of the Tcb gene cluster and Tcb locus have only been determined for plants in which said gene cluster and loci were derived from W22-TCB, which is the result of the cross of a particular Zea mays plant and a particular teosinte accession, each of a particular genotype. The confusion in the specification as to the actual composition of the Tcb gene cluster, including the presence or absence of the modifier gene and other genes, as discussed previously and below; reinforces the Examiner's position that no guidance has been provided regarding any conserved sequences which are correlated with Tcb gene cluster function or Tcb locus function, which are conserved throughout the broadly claimed genus of any Tcb locus, any Tcb gene cluster, any "modifier" gene, any "pollen effect" gene, and any "silk effect" gene from any plant resulting from the cross of any two parents.

Regarding the modifier gene, the Examiner notes that page 16 of the specification, lines 23-29, state that "the inventors *believe* that at least one modifier gene...is located about 6.5 map units...from the Tcb locus", and that "[o]ther modifier genes..are located ...*outside* the gene cluster on chromosome 4... or on *one or more* chromosomes *other than* chromosome 4" [emphasis added]. Thus, only anecdotal reference to the supposed location of one modifier gene is demonstrated, and the genus is stated to encompass any modifier gene on any chromosome. No molecular

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markers have been described which would be useful for isolating any of the putative modifier genes.

It is also noted that an assay for *finding* a product is not equivalent to a positive recitation of *how to make* a product. Alternatively, disclosure of a method for producing a product does not reduce to practice the product itself. See *Bayer v. Housey*, Appeal No. 02-1598, (Fed. Cir. 2003), decided 22 August 2003, penultimate page: "processes of identification and generation of data are not steps in the manufacture of a final [drug] product". Such a reduction to practice is required for the skilled artisan to have recognized Applicant to have been in possession of the claimed invention.

Claims 9-17, 21-26, 39-50 and 59-68 remain, and new claims 73-80 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to maize plants containing the TCB trait from maize line W22-TCB (ATCC No. PTA-1601) and methods of using them, does not reasonably provide enablement for claims broadly drawn to any maize plant containing any TCB trait or gene cluster, any Tcb locus, any "modifier gene", any "pollen effect" gene, any "silk effect" gene, or methods of using them. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on pages 2-3 of the last Office action for claims 9-17, 21-26, 39-50 and 59-68.

Applicant's arguments filed 15 March 2004 have been fully considered but they are not persuasive. Applicant urges that the specification provides molecular markers useful for determining whether the Tcb gene cluster or Tcb locus is present in any

maize plant derived by crossing two other plants, as well as providing the location of the relevant genes in the genome of a single plant derived by crossing a single teosinte genotype and single Zea mays genotype, namely W22-TCB. Applicant urges that such information precludes undue experimentation.

The Examiner maintains that it is unclear what the Tcb locus and Tcb gene cluster comprise, even in the exemplified W22-TCB. Page 7 of the specification indicates that the Tcb gene cluster may or may not contain a modifier gene (lines 21-22, note the recitation "and/or"). Page 16 of the specification, lines 23-24 indicates that the Tcb gene cluster "*can also contain at least one modifier gene*" [emphasis added]. Thus, it is unclear whether or not the Tcb gene cluster actually contains one or more modifier genes, given the contradictory statements in the specification. In view of such contradiction, one skilled in the art would not have been able to utilize any molecular marker putatively associated with a modifier gene which may or may not comprise the claimed invention.

In addition, molecular markers which are clearly associated with even one modifier gene, let alone non-exemplified modifier genes on different loci within chromosome 4 or on different chromosomes, have not been disclosed. Even had they been disclosed, the mere provision of an assay (i.e. molecular markers and proposed methods for their use) is insufficient to provide one skilled in the art with the actual product (namely corn plants which contain the Tcb locus or Tcb gene cluster which were obtained by crossing a multitude of non-exemplified parents). See *Bayer* cited above.

Furthermore, the Examiner maintains that Goldman et al, previously cited, clearly demonstrates that the choice of parents greatly influences the location of molecular markers on particular chromosomes. Applicant has not provided any molecular marker data for any plants which allegedly contain the Tcb locus or Tcb gene cluster, wherein said Tcb locus or Tcb gene cluster was obtained by crossing two parents other than the parents of W22-TCB.

Claims 1-5, 9-17, 21-35, 39-50, 59-66 and 69-72 remain, and newly submitted claims 74, 77 and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Kermicle et al (1990), as stated on page 3 of the last Office action.

Newly submitted claims 74, 77 and 79 are included in the rejection, because the molecular marker-assisted process of making maize plants containing a Tcb gene cluster or Tcb locus does not confer a distinguishing characteristic to the resultant plants which contain a Tcb gene cluster or Tcb locus, wherein such plants were taught by the prior art.

See In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Applicant's arguments filed 15 March 2004 and 15 April 2004 have been fully considered but they are not persuasive.

Applicant urges that Kermicle et al (1990) does not teach a Tcb locus or Tcb gene cluster, since the plants taught by Kermicle et al comprised a TIC-CP1 gene not



found in the Tcb locus or Tcb gene cluster. Applicant further urges that Kermicle et al (1990) did not elucidate the existence or location of any "silk effect" gene or any "modifier gene", or provide molecular markers useful for determining their presence. Applicant refers to the Kermicle declaration of 15 April 2004.

The Examiner maintains that the allegation that the Tcb locus or Tcb gene cluster do not contain the TIC-CP1 gene taught by Kermicle et al (1990), as also set forth in the Kermicle declaration of 15 April 2004, contradicts other statements in the specification.

Page 16 of the specification states that the Tcb locus comprises gene(s) encoding a "pollen effect" (lines 9-10); see also page 17, lines 12-14. Page 17 of the specification indicates that the TIC-CP1 gene(s) "is associated with the pollen effect function Tcb" (lines 6-7). Thus, these statements contradict the assertion that the Tcb locus does not contain TIC-CP1.

Furthermore, page 17 of the specification teaches that W22-TCB contains "the gene cluster described herein", including "the Tcb locus and at least one gene(s) which encode for the silk and pollen effect functions and at least one modifier gene", and "W22-TCB also contains "TIC-CP1" (see lines 17-22). Thus, page 17 of the specification indicates that a plant that contains the Tcb locus also contains the TIC-CP1 gene.

Furthermore, the Examiner notes that Kermicle et al (1990) teach the presence of TIC-CP2 in their plants (see, e.g., page 405, Figure 3 and page 406, Figure 4), while Figure 4B of the instant specification also teaches the presence of this gene in the instant gene cluster conferring the TCB trait.

As stated previously, the parentage of W22-TCB and the parentage of the plants disclosed in Kermicle et al (1990) appear to be identical, namely the Zea mays inbred W22 and the teosinte accession No. 48703 (see, e.g., Kermicle et al [1990], page 401, column 1, bottom paragraph). Although the instant specification further characterizes the molecular markers associated with the Tcb locus, as well as the existence of putative modifier gene(s), the Examiner maintains that no evidence has been provided that Kermicle et al (1990) did not disclose a plant with the same genetic complement as W22-TCB. The further characterization of the prior art plant with respect to the presence of molecular markers or modifier genes does not confer patentable distinction to the plant itself, which was characterized by Kermicle et al (1990) as containing "additional factors", and which is characterized in the instant specification as indeed containing TIC-CP1.

Furthermore, Kermicle et al (1990) do teach the analysis of DNA for the presence of the CP2 gene in relation to other chromosomal loci including su1, Ts5, Ga1 and the centromere (see, e.g., page 405, Figure 3). Claims drawn specifically to the instantly disclosed molecular markers and their use, namely claims 73 and 78, were not included in the art rejection under 35 USC 102.

Claims 1-5, 9-17, 21-35, 39-50, 59-68 and 69-72 remain, and newly submitted claims 74-77 and 79-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kermicle et al (1990) taken with Nelson, as stated on page 3 of the last Office action.

Claims 75-77 and 80 are included in this rejection since Nelson teaches methods for crossing maize plants comprising cross-incompatibility traits in order to

produce inbreds and hybrids, wherein the plants taught by Kermicle et al (1990) inherently possess the molecular markers recited in claims 73 and 78.

See also *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993), which teaches that a reference teaching a claimed process, wherein one of the claimed properties of a product used in the prior art process is inherent but undisclosed by the reference, may be properly applied as art against the claimed process.

Applicant's arguments filed 15 March 2004 and 15 April 2004 have been fully considered but they are not persuasive. Applicant urges that Nelson does not cure the deficiencies of Kermicle et al (1990) by disclosing the particularly claimed Tcb gene cluster or Tcb locus, or methods of crossing plants containing them.

The Examiner maintains that Nelson teaches the general advantages of crossing maize plants containing cross-incompatibility factors, including those taught by Kermicle et al (1990), for the controlled production of inbreds and hybrids, as discussed previously. Furthermore, many of the claims are not limited to any particular Tcb gene cluster or Tcb locus at any particular chromosomal location or derived from any particular parental plants (see, e.g., claims 15-17, 39, 41, 43-50, 59, and 67-68).

See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

Claims 73 and 78 are deemed free of the prior art, given the failure of the prior art to teach or suggest methods for using or assaying for the particularly claimed molecular markers to identify the Tcb locus or the Tcb gene cluster.

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No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

May 30, 2004

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP ~~180~~ 1638

A handwritten signature in black ink, appearing to read "David T. Fox", written in a cursive style.